

What is claimed is:

- 5
1. A device for sampling body fluid, comprising:
- a) a main body defining a capillary channel;
 - b) a lancet disposed within said capillary channel and defining
- an annular space between said lancet and said main body;
- c) wherein said lancet is selectively advancable and retractable;
- and,
- d) wherein said capillary channel is dimensioned to draw a body
- fluid into said annular space through capillary action.
- 10
2. The device of claim 1 further comprising at least one testing element in communication with said annular space.
3. The device of claim 2 wherein said testing element is a test strip.
- 15
4. The device of claim 3 wherein said test strip is a membrane.
5. The device of claim 3 wherein said test strip is radially mounted around said lancet.
- 20
6. The device of claim 3 wherein said test strip is mounted in a groove defined in said lancet.

10054270, 012202

5/21

7. The device of claim 3 wherein said test strip is mounted in a groove defined in said main body.

8. The device of claim 2 further comprising two or more testing
5 elements in communication with said annular space.

9. The device of claim 2 wherein said testing element comprises electrochemical sensors within said annular space.

10. The device of claim 2 further comprising biasing means to
10 selectively retract said lancet.

11. The device of claim 10 further comprising biasing means to
15 selectively advance said lancet.

12. The device of claim 10 wherein said biasing means is a spring operable to provide relative movement between said lancet and said main body.

20 13. The device of claim 12 wherein said spring is mounted within said capillary channel between a bearing surface on said main body and a bearing surface on said lancet.

202310054270.012202

14. The device of claim 13 wherein said spring comprises a bio-compatible material.

5 15. The device of claim 2 wherein said main body has a generally cylindrical shape.

16. The device of claim 15 wherein said main body comprises a bio-compatible plastic.

10 17. The device of claim 3 wherein said test strip is optically reactive.

18. The device of claim 17 wherein at least a portion of said main body adjacent said test strip is transparent.

15 19. The device of claim 17 wherein said main body is transparent.

20 20. The device of claim 2 wherein said main body defines a distal opening to said capillary channel and wherein said device further comprises a tip covering said opening and penetrable by said lancet.

21. The device of claim 2 wherein said lancet advances from said main body a distance between approximately 0.05 mm and 3 mm.

22. A system for sampling and testing a body fluid, comprising:

10054270.012202

- a) a main body defining a capillary channel;
- b) a lancet disposed within said capillary channel and defining an annular space between said lancet and said main body;
- c) wherein said lancet is selectively advancable and retractable;
- 5 d) wherein said capillary channel is dimensioned to draw a body fluid into said annular space through capillary action; and,
- e) a testing means for testing the body fluid drawn into said capillary channel.

10 23. The system of claim 22 wherein said testing means comprises at least one test element in communication with said annular space.

24. The system of claim 22 wherein said testing means comprises analysis equipment operable to test the body fluid in said annular space.

15

25. The system of claim 25 wherein said testing means further comprises electrochemical sensors mounted within said annular space and in communication with said analysis equipment.

20 26. The system of claim 24 wherein said main body is placed in said analysis equipment after a body fluid sample is collected.

27. The system of claim 26 wherein said testing device tests the body fluid using optical transmittance, reflectance or fluorescence.

10054270.01.2202

28. The system of claim 26 wherein said testing device tests the body fluid using electrochemical sensors situated to communicate with said annular space.

5

29. A device for sampling body fluid, comprising:

- a) a base unit;
- b) a disposable main body mountable to said base unit and defining a capillary channel;
- 10 c) a lancet disposed within said capillary channel and defining an annular space between said lancet and said main body;
- d) injection means associated with said base unit and releasably coupleable to said lancet, wherein said injection means is operable to selectively advance and retract said lancet; and,
- 15 e) wherein said capillary channel is dimensioned to draw a body fluid into said annular space through capillary action.

20

30. The device of claim 29 further comprising testing means in communication with said annular space for analyzing the body fluid.

31. The device of claim 30 wherein said testing means comprises electrochemical measuring equipment associated with said base unit.

202210-0245001

32. A method of obtaining a fluid sample from the body of a person, comprising the steps of:

a) placing an apparatus having a defined capillary channel adjacent tissue at a desired sample location;

5 b) advancing a lancet disposed within said capillary channel so that said lancet incises tissue at an incision point in the desired sample location;

c) retracting said lancet into said capillary channel; and,

10 d) acquiring body fluid expressed from the body at the incision point into said capillary channel through capillary action.

33. The method of claim 32 further comprising the step of testing the acquired body fluid while the fluid is contained in said capillary channel.

15 34. The method of claim 32 further comprising the step of transferring the fluid from said capillary channel to a testing element and thereafter testing the fluid.

20 35. The method of claim 32 further comprising the step of testing the acquired body fluid with testing means communicating with said capillary channel.

36. The method of claim 33 further comprising the step of testing the acquired body fluid for a blood glucose level.

202210-0245001

37. A device for measuring blood glucose levels, the device comprising:

a) a main body having a generally cylindrical shape, a proximal end and a distal end;

5 b) a lancet disposed within said main body, wherein an annular space is disposed about said lancet and defined by said main body, and said lancet protrudes beyond said distal end of said main body; and,

c) a means for testing blood glucose levels in communication with said annular space.

10

38. The device of claim 37, wherein said means for testing blood glucose levels comprises an electronic meter disposed adjacent said proximal end of said main body and having sensors in communication with said annular space.

15

39. A method for sampling a body fluid, comprising the steps of:

a) providing a testing apparatus with a main body defining a capillary channel, and a lancet disposed within said capillary channel and defining an annular space between said lancet and said main body;

20 b) placing the testing apparatus over a site to be lanced;

c) advancing said lancet into the site thereby creating an incision;

and,

d) withdrawing a body fluid into said annular space through capillary action.

1054270.012208

40. The method according to 39 further including the step of withdrawing said lancet from said incision prior to withdrawing the body fluid.

5

41. The method according to claim 40 wherein said lancet is withdrawn to between 0 and 2 mm from said site.

10

42. The method according to claim 39 in which said lancet is movable relative to said main body.

43. The method according to claim 39 in which said lancet is fixed in position relative to said main body.

202310-012202